DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

Food and Drug Administration
Denver District Office
Bldg. 20-Denver Federal Center
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6th Avenue & Kipling Street
Denver, Colorado 80225-0087
Telephone: 303-236-3000
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January 16, 2003

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT

Mr. Stephen N. Xenakis
President/CEO
Lexicor Medical Technology, Inc.
3540 Wheeler Executive Park, Suite 505
Augusta, Georgia 30909

Ref#: Den 03-10

Dear Mr. Xenakis:

We are writing to you because on July 3 through 17, 2002, an investigator from the Food and Drug Administration (FDA) collected information that revealed a serious regulatory problem involving the product known as "DataLex" web portal which is made and marketed by your firm. This software product is promoted on Internet websites for DataLex and Lexicor, and uses data from your XXXXXX to diagnose Attention Deficit Hyperactive Disorder (ADHD) in humans.

We are also responding to your letter of July 17, 2002, to our investigator at the Denver District Office, in which you wish to clarify the overall development of the DataLex web portal.

Under a United States Federal law, the Federal Food, Drug, and Cosmetic Act (Act), this product is considered to be a medical device because it is used to diagnose or treat a medical condition or to affect the structure or function of the body. Specifically, the product is promoted for use in diagnosing ADHD. The law requires that manufacturers of medical devices obtain marketing clearance for their products from FDA before they may offer them for sale. This helps protect the public health by ensuring that new medical devices are shown to be either safe and effective or substantially equivalent to other devices already legally marketed in this country.

Our records do not show that you obtained marketing clearance before you began offering your product for sale. The kind of information you need to submit in order to obtain this clearance is described on FDA's device web site at WWW.FDA.GOV/CDRH/DEVADVICE. The FDA will evaluate this information and decide whether your product may be legally marketed.

Because you do not have marketing clearance from the FDA, marketing your product is a violation of the law. In legal terms, the product is adulterated under section 501(f)(1)(B) and misbranded under section 502(o) of the Act. Your product is misbranded under the Act because you did not submit a section 510(k) premarket notification that shows your device is substantially equivalent to other devices that are legally marketed. Until you submit a section 510(k) premarket notification and FDA reviews it and notifies you that you may market your device, your product is also adulterated under the Act because the law requires, and you do not have, an approved premarket approval application that shows your device is safe and effective.

For your information, the above stated inspection also revealed your devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820. The deviations include: formal procedures for management review have not been established; a management representative has not been appointed; change control procedures do not require verification of design changes; and there are no procedures addressing preventive actions.

You should know that these serious violations of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. Also, other Federal agencies are informed about the warning letters we issue, such as this one, so that they may consider this information when awarding government contracts.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you receive this letter what steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to Ms. Shelly L. Maifarth, Compliance Officer, at the letterhead address.

If you have more specific questions about how FDA marketing requirements affect your particular device, or about the content of this letter, please feel free to contact Ms. Maifarth at (303) 236-3046.

Sincerely yours,

Karen E Kreuger
for

B. Belinda Collins
Director
Denver District Office
Food and Drug Administration